Science for Communities

HEALTH RISK ASSESSMENT: LEAD IN CHILDREN'S TOYS

May 2021

Jeff Fowles

PREPARED FOR: Ministry of Health
CLIENT REPORT No: FW21014
REVIEWED BY: Peter Cressey

Manager	Peer Reviewer	Author
		
Rob Lake	Peter Cressey	Jeff Fowles
Risk Assessment & Social Systems Group Institute of Environmental Science and Research		Tox-Logic

DISCLAIMER

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

EXECUTIVE SUMMARY

Lead (Pb) exposures can cause lasting neurological effects in children, most notably a reduction in cognitive ability and IQ. While population-wide exposures to Pb from environmental sources have been generally decreasing over decades in New Zealand due to the removal of Pb in petrol, paints and tinned canned foods, some sources of Pb remain a concern for child exposures in some areas. Legacy soil and dust contamination with old paint from houses built prior to 1980 still has potential to present an exposure route of concern.

Toys come into frequent direct contact with a child's skin and mouth, and thus are of concern for any potential to be a vehicle for Pb exposure. Existing standards for Pb in children's toys (90 ppm) have been in place in New Zealand since 2009 and are consistent with similar standards for toys and coated children's products internationally. Most toys are not expected to contain any Pb. Nevertheless, some non-compliant toy products could pose a significant risk. The basis for the 90 ppm Pb allowable limit has been to prevent exposures that would elevate children's blood Pb levels above the previous threshold value of 0.48 μmol/L (10 μg/dL). However, a child's blood Pb level of 0.24 μmol/L (5 μg/dL) has recently become the accepted public health notification level for Pb exposure in children.

In this report, three exposure scenarios were explored:
1) Exposure to toys containing Pb at the allowable limit of 90 ppm,
2) Exposure to toys with published migration of Pb using wipe sample (0.7 μg Pb/wipe), and
3) Swallowing a 1 g toy at the 90 ppm allowable limit.

Exposures, using conservative assumptions, were determined to be of potential concern for a child exceeding 0.24 μmol Pb/L in blood. While Pb in toys is not a population-wide health concern, it can represent significant hazard to individual children who may come into contact with non-compliant toys.

1. INTRODUCTION

The purpose of this report is to review the literature and develop a generic health risk assessment for toys containing lead (Pb). This report will only consider domestic, non-occupational, routine and incidental exposure to Pb from use of toy products. New Zealand and international regulatory limits for Pb in children's toys are reviewed. It is not the purpose of this report to comprehensively review the toxicological hazards of Pb and the authoritative hazard values established internationally.

A detailed exposure assessment of Pb from food, water, air, or other environmental sources of exposure is not presented in this report. Exposure scenarios are described for exposure events that could result in Pb exposure from toys and the associated health risks from these exposures are characterised.

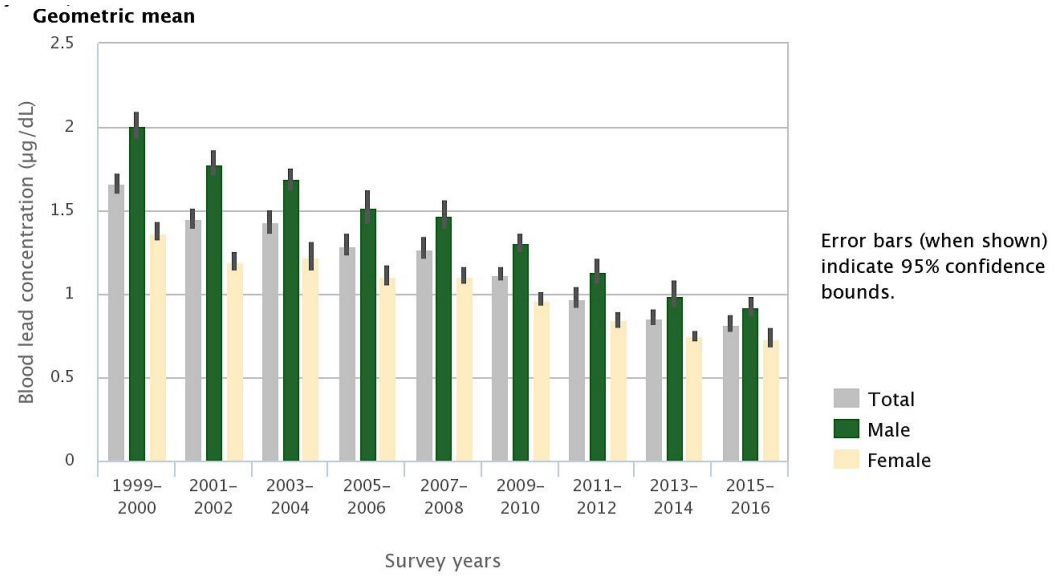
1.1 LEAD EXPOSURES AND CHILDREN'S HEALTH

Lead is a developmentally neurotoxic heavy metal, with a vast amount of epidemiological and toxicological literature describing the ability of Pb to interfere with brain development in children, resulting in altered behavior and lowered Intelligence Quotient (IQ) (Budtz-Jorgensen et al 2013; Lanphear et al 2005). The dose-response relationship for this effect is well established and supported in the literature. The regulation of Pb is different from most other environmental contaminants, in that the derived allowable levels from various sources are driven by the need to maintain children's blood Pb levels to less than an acceptable level.

Children, infants, and fetuses are more vulnerable to the effects of Pb because their blood brain barrier is not fully developed (USEPA 2018). Thus, a smaller amount of Pb will have a greater effect on children than on adults. In addition, Pb absorption can be up to five times greater in children compared to adults. Currently, no level of Pb in blood has been identified as safe in children. Rather, the U.S. Centers for Disease Control and Prevention (CDC) has established a "reference level" of 5 micrograms per deciliter (µg/dL) to be used to identify children with elevated blood Pb levels. The reference level is based on the 97.5th percentile of the blood Pb level distribution in U.S. children aged 1-5 years in the NHANES database (CDC 2012).

There has been a decreasing trend in blood Pb in New Zealand. Overall there has been a 90% reduction in the blood Pb for the New Zealand population since the 1970s, due primarily to the removal of Pb in petrol and in soldered tin cans ('t Mannetje et al 2020). While the Pb content of paint has also been substantially reduced during this period, many New Zealand houses still contain Pb-based paints and it is uncertain whether the changes in the Pb content of paint has contributed to the decrease in blood Pb. This trend follows a similar trend in the U.S. (Council on Environmental Health 2016). In a biomonitoring survey from 2014-2016, the geometric mean blood Pb in 191 New Zealand children age 5 to 18 years old was 0.86 µg/dL ('t Mannetje et al 2020). In comparison, children in the U.S., in a 2015-2016 survey, had a slightly lower geometric mean blood Pb level of 0.758 µg/dL (ages 1-5) (Figure 1) and 0.57 µg/dL (ages 6-11). It is not clear if this difference is statistically significant, and the age range in these groups are not precisely matched to allow a robust comparison. Nevertheless, on a population basis, the U.S. and New Zealand appear to be reasonably closely matched in this metric.

Figure 1. Decreasing geometric mean blood Pb concentrations in U.S. children aged 1-5 years

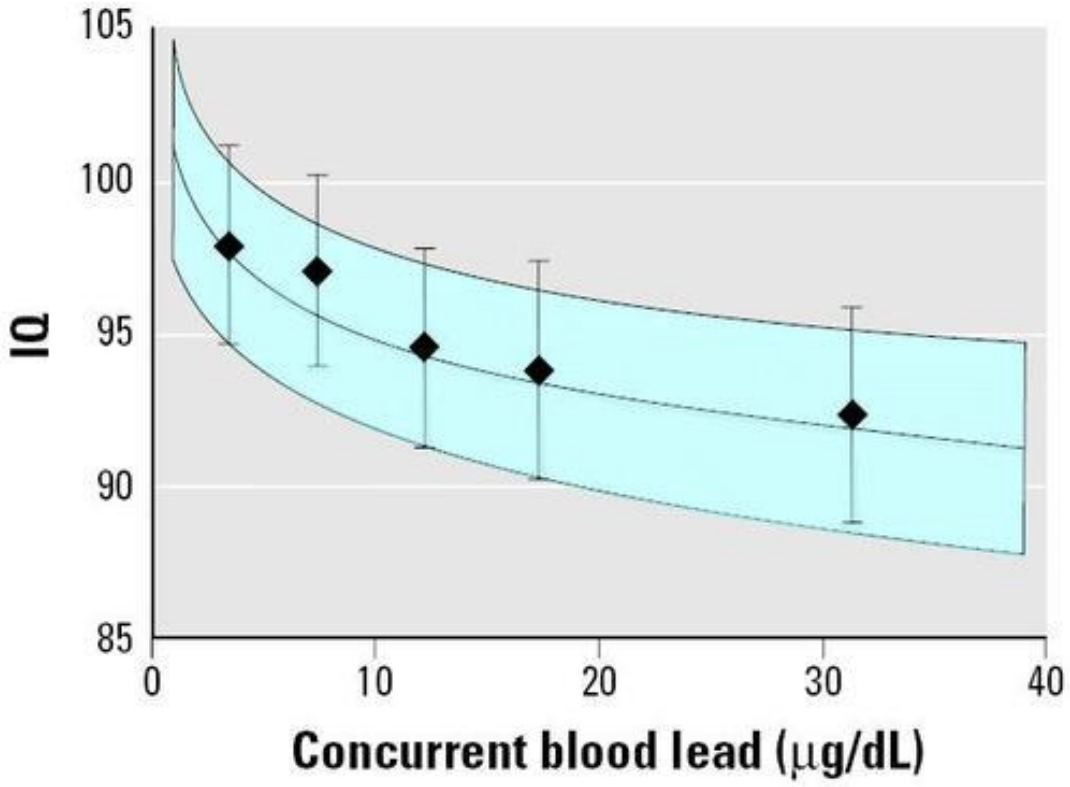


Source: USEPA (2018)

Previously a blood Pb level of 10 µg/dl (0.48 µmol/L) had served as the notification level for Pb in adults and children in New Zealand. In 2021, the U.S. CDC blood Pb reference level of 0.24 µmol/L (5 µg/dL) has been implemented as a notification level in New Zealand to mitigate the health impacts in children (Table 1) (Ministry of Health 2021). The U.S. CDC is reportedly considering lowering the notification level further to 3.5 µg/dL (Zartarian et al 2017), although at the time of this report, this appears to be still under consideration.

The relationship between blood Pb levels and adverse human health outcomes has been extensively reviewed and assessed as a quantitative relationship where an increase of 1-2 µg/dL in blood Pb equates to a deficit of 1 IQ point (CalEPA 2009; SNC-Lavalin 2012). The Joint Expert Committee on Food Additives and Contaminants (JECFA) estimated that a daily dose of Pb of 0.3 µg Pb/kg BW/day would lead to a deficit of 0.5 IQ points (JECFA 2011). Figure 2 below illustrates the non-threshold nature of the relationship between blood Pb and IQ.

Figure 2. Blood Pb relationship with IQ declines for children



Adopted from Lanphear et al (2005)

While the aim of public health efforts is to keep children's blood Pb levels below a specified concentration, the fact that there is no known threshold for the adverse effects of Pb, combined with the decreasing trend in population Pb levels, means that an "As Low As Reasonably Achievable" (ALARA) approach essentially governs most Pb risk management activities.

1.2 BLOOD LEAD NOTIFICATION LEVELS

The notification level for a lead-exposed child has changed in recent years in the U.S., New Zealand, and Australia from 0.48 μmol/L to 0.24 μmol/L, while in Canada and the UK, the previously developed notification levels remain (Table 1).

Table 1. Blood Pb Notification Levels

Authority	Blood Pb notification level
New Zealand[1] Australia[2] U.S.A.[3]	0.24 μmol/L (5 μg/dL)
U.K.[4] Canada[5]	0.48 μmol/L (10 μg/dL)

[1] Ministry of Health (2021); [2] NSW Health (2018); [3] CDC (2012); [4] Public Health England (2020); [5] Health Canada (2013)

2. CONCERNS ABOUT LEAD EXPOSURES FROM CHILDREN'S PRODUCTS

2.1 NEW ZEALAND CONCERNS

In 2010, an article in the New Zealand Herald described "Highly Toxic Lead Levels in Toys" (NZ Herald 2010). The article listed several painted toys purchased from bargain stores in New Zealand, with Pb migration levels exceeding the New Zealand allowable migration limit for Pb in toys of 90 mg Pb/kg, with some concentrations over 28,000 mg Pb/kg.

A recall of 150 painted nesting doll toys purchased through Trade Aid in New Zealand, occurred in 2017 due to detected, but undisclosed levels of Pb (Winter 2017). Other products, also obtained from India in the same shipment, were tested and found to be free of detectable Pb. The presence of Pb in these products was attributed to a change in paint used in manufacture.

2.2 INTERNATIONAL CONCERNS

Lead is used to augment paints and pigments on some toys. Toys themselves may be made of lead. Under the 1973 Federal Hazardous Substances Act, the US Consumer Product Safety Commission (CPSC) banned hazardous amounts of lead in toys and other products intended for use by children and required warning labels on other lead-containing products. In 1978, the CPSC banned furniture, toys, and other articles with a surface lead content of 0.06% or higher by weight intended for use by children.

One of the first indications that children's toys could be an important route of exposure to Pb, arose from a Greenpeace 1997 report on dislodgeable Pb residues from polyvinyl chloride (PVC) based toys, and a follow up report by the U.S. CPSC (CPSC 1997; Di Gangi 1997). Although the CPSC concluded that there was no significant hazard from the toys tested, some of the items clearly demonstrated a significant ability to transfer Pb in contact with a moist wipe. In one toy accessory to a Barbie™ set, a toy phone cord yielded 0.7 μg Pb per wipe, which, employing a 50% hand-to-mouth transfer efficiency, resulted in an estimated 43 wipes to achieve a daily dose of 15 μg Pb/day. The CPSC appeared to not consider the addition of exposure to Pb from toys to the existing background Pb exposures from food, water, or soil, to be significant. The 1997 CPSC report cites ASTM F 963-96 and EN 71-3 test methods for meeting a surface coating limit of 90 μg Pb/g (90 ppm), based on the 15 μg Pb/day intake as a dose level corresponding to a steady state blood Pb level of 10 μg/dL (CPSC 1997). The wipe tests performed by CPSC indicated that the dislodgeable Pb from the PVC items tested would not exceed 15 μg Pb/day.

In a review on the topic of Pb exposure and toxicity from vinyl and painted toys, the CPSC was quoted as using 175 μg Pb/day intake as corresponding to a 10 μg/dL blood Pb level (Schmidt 2008). It is unclear how the 175 μg Pb/day relates to the more widely referenced 15 μg Pb/day dose level, both of which are said to result in an expected 10 μg Pb/dL in blood. In one case, a child in the U.S. reportedly died from Pb poisoning by ingesting a small toy with high Pb levels in the paint (Muscat 2020; Schmidt 2008). For comparison, the

JECFA analysis estimated that dietary exposure to Pb of 1 μg/day equated to a blood Pb level of 0.023-0.07 μg/dL (JECFA 2011). On this basis, a blood Pb level of 10 μg/dL would equate to an exposure of 140-430 μg/day.

Despite this conclusion, concerns remained, and the Consumer Product Safety Improvement Act of 2008 (Public Law 110-314) came into force in 2008. This law limits total Pb content of children's products (including toys) to 100 ppm (mg Pb/kg material), and 90 ppm specifically for coatings (CPSC 2021). The toxicological basis for these numerical limits could not be found, but appears to be due to legislation that was proposed in 2007 in the U.S. to gradually lower the Pb standard in toy from 600 ppm to 100 ppm over a period of 4 years (Schmidt 2008). The 90 ppm Pb allowable limit appears to be based on preventing a daily intake of 15 μg (Schmidt 2008).

Despite the development of these U.S. laws, many products containing Pb still enter the marketplace. From 1977 to 2014, the CPSC issued 350 recalls of more than 200 million consumer items for violations of the Pb paint standard or other Pb exposure risks (Dignam et al 2019).

The latest revision of the toy safety standard in the U.S. was in 2017, in which safety testing for toys was required to meet ASTM standard ASTM F963 for toys, using the same criteria (15 μg/day) for acceptable Pb estimated intakes (CPSC 2017).

According to Product Safety Australia:

"Toys are one of the most common sources of lead poisoning in children.

Young children often place toys in their mouth to explore them by sucking, mouthing and chewing on them. If children suck, chew on or swallow on a toy containing unsafe levels of lead or other harmful elements, they can suffer significant and sometimes permanent damage to their physical and mental health. In some cases, they can die.

As children apply finger paints with their hands, they are likely to absorb or ingest substantial amounts of paint. This is why finger paints can easily expose children to various harmful elements, including lead. If children consume finger paints containing lead, or if they inhale lead or absorb it through their skin, they can suffer significant and sometimes permanent damage to their physical and mental health. In some cases, they can die." (Product Safety Australia 2021).

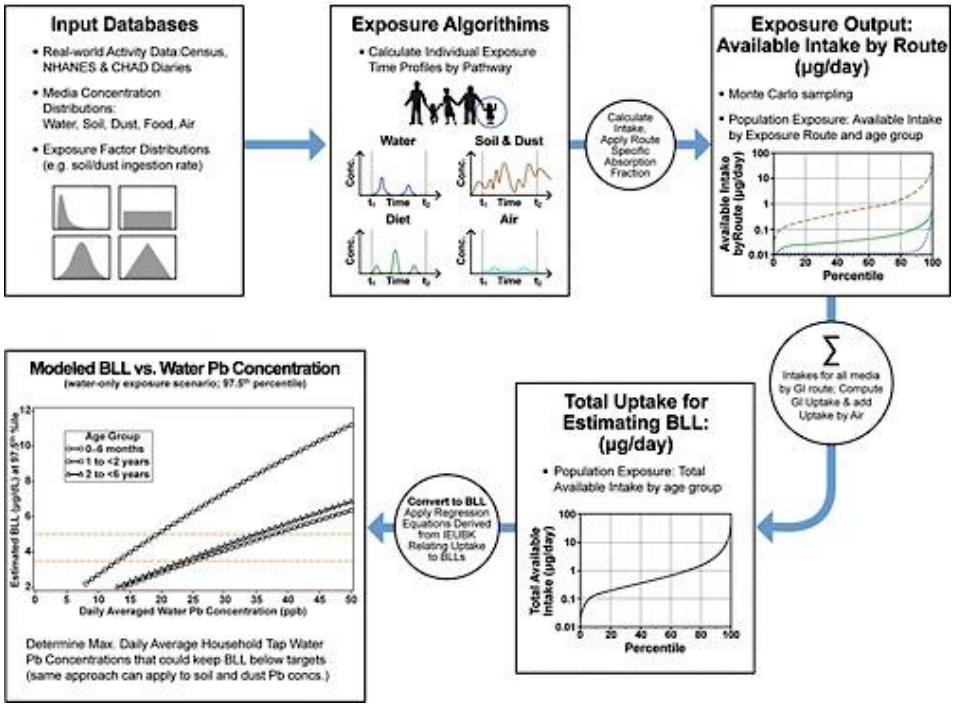
The European RAPEX system for reporting product safety regulatory concerns and recalls has numerous entries for Pb non-compliance in toys and children's products, the majority of them originating from items manufactured or imported from China. While notifications of Pb contaminated toys can be found in the RAPEX system, the vast majority are not expected to pose any Pb exposure or risk, and at least one survey of Portuguese toys found that none of those tested exceeded the EU allowable Pb limits (Leal et al 2016). The EU in 2018 lowered its allowable Pb in children's toys due to evolving concerns that such items contribute to individual children's risks of excessive Pb exposure (SGS 2017).

3. ENVIRONMENTAL SOURCES OF LEAD EXPOSURE IN CHILDREN

It is important to frame any exposures from Pb in toys against the context of background Pb exposures from other sources in the environment. Due to the widespread occurrence of Pb in the environment, including the food supply, drinking-water, soils/dusts, and occupational settings, risks and exposures to Pb are typically placed into context of daily exposures from all sources. It is not the purpose of this report to explore or describe the vast literature on Pb environmental levels, regulations, and exposures, but a summary of key exposure routes is presented.

A conceptual illustration of the multimedia approach to assessing Pb intakes and risks from environmental sources is shown in Figure 3 below.

Figure 3. Illustration of how environmental exposure pathways for Pb are modeled to understand their impact on total daily dose



Adopted from Zartarian et al (2017)

The study by Gulson and colleagues (2018) reported that the geometric mean contributions of daily Pb exposures from different environmental media to 108 toddlers (1-2 year old) in Sydney, Australia, were: 0.09%, 42%, 5.3%, and 42% for air, diet, water, and dust/soil, respectively (Figure 4). The authors of this study did not comment on the fact that the sum of the mean contribution was less than 100%. However, this may have been due to their decision to calculate geometric, rather than arithmetic means.

3.1 DIET

The diet is considered to be a major source of Pb exposure in the general population (ATSDR 2021; Gulson et al 2018). In the U.S., a published estimate of mean dietary Pb exposures in children aged 1-6 years old ranged from 1 to 3.4 µg/day (0.06 to 0.23 µg/kg bw per day or 0.42 to 1.6 µg/kg bw per week), with major contributions from grains, fruit, dairy, and mixtures (e.g. hamburgers, pizza, lasagna, soups) (Spungen 2019).

Similar dietary exposure estimates for New Zealand are available from the New Zealand Total Diet Study (NZTDS) (Pearson et al 2018). Estimated dietary exposure to lead for toddlers (1-3 years) and children (5-6 years) are in the range 0.53 to 2.2 µg/kg bw per week.

In 2018, the U.S. Food and Drug Administration (US FDA) lowered its Interim Reference Level (IRL) for Pb intakes from food sources from 6 µg/day to 3 µg/day, based on modeled exposures leading to a steady state blood Pb of 5 µg/dL (Table 2) (USFDA 2020). Other organisations have developed daily dose limits that correspond to specified increases in blood Pb and the corresponding decrease in IQ (Table 2).

Table 2. Daily Intake Reference Values for Pb

Agency	Allowable or Estimated Intake	Date	Comment
U.S. FDA[1]	3 µg Pb/day (foods) (children) 12.5 µg Pb/day (foods) (adults)	2020	Lowered from 6 Calculated to result in PBB = 5 g/dL
New Zealand (Total Diet Survey)[2]	0.53-2.19 µg Pb/kg bw/week (children) 0.22-0.91 µg Pb/kg bw/week (adults)	2016	Estimated weekly Pb intakes from the NZ TDS, 2018
Health Canada[3]	0.6 µg Pb/kg bw/day (children < 11 yo) 1.3 µg Pb/kg bw/day (adults)	2013	Proposed allowable daily intakes
WHO (JECFA)[4]	0.6 µg Pb/kg bw/day (children < 11 yo) 1.3 µg Pb/kg bw/day (adults)	2011	Estimated dose for blood Pb increase needed for 1 IQ point decrease (children); increase in blood pressure by 1 mm Hg (adults)
Cal/EPA[5]	0.6 µg Pb/kg bw/day (children < 11 yo) 1.3 µg Pb/kg bw/day (adults)	2009	Estimated dose for blood Pb increase needed for 1 IQ point decrease (children); increase in blood pressure by 1 mm Hg (adults)
EFSA[6]	1.2 µg Pb/kg bw/day	2010	Estimated dose for blood Pb increase needed for 1 IQ point decrease (children); increase in blood pressure by 1 mm Hg (adults)

[1] USFDA (2020), [2] Pearson et al (2018), [3] Health Canada (2013), [4] JECFA (2011), [5] CalEPA (2009), [6] EFSA (2010)

3.2 DRINKING-WATER

Drinking- water typically is expected to present a small fraction of the daily Pb exposure for most people (Gulson et al 2018). Some exceptional cases to this generalization may arise when local water supplies are contaminated with Pb at levels that exceed the drinking water standards. In New Zealand, the maximum allowable value (MAV) of Pb in drinking water is

0.01 mg/L, which, using estimated mean daily water consumption statistics, would equate to 0.004 mg/day (4 μg/day), for a 5-6 year old New Zealand child (Cressey and Horn 2016).

3.3 SOILS/DUST

Dust and soils can contribute markedly to Pb exposure of many young children, depending on factors specific to the age and composition of their home, and the amount of Pb in the soils they come into contact with regularly (Gulson et al 2018). A study of house dust Pb levels in 120 Christchurch homes found a geometric mean of 573 mg Pb/kg (Kim and Fergusson 1993). Petrol Pb and leaded paints were identified as major contributors to the house dust Pb concentrations. A study of children in New South Wales urban areas found that modeled exposure contributions from dusts and soils were approximately equal to that from dietary sources (Gulson et al 2018), and a survey of 224 Sydney homes found house dust Pb to have a mean concentration of 299 mg Pb/kg, and the 95th percentile of 364 mg Pb/kg (Doyi et al 2019). Children in these homes had predicted blood Pb levels that exceeded 5 μg/dL in 19.2% of cases. Using the default Australian dust intake parameter of 50 mg/day (Doyi et al 2019), mean daily Pb intakes from house dust in these homes would be 15 μg/day. In other studies in rural agricultural areas, the contribution to Pb exposures from dusts and soils has been found to be substantially less, again depending on whether homes were built prior to 1980 or are primarily made from brick rather than painted wood (Gulson et al 2018).

3.4 AIR

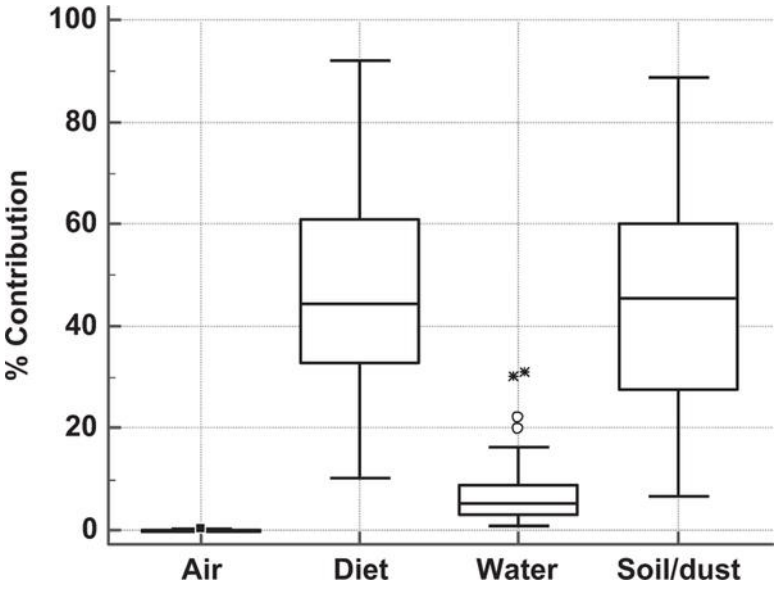
Since the elimination of Pb in petrol, the exposure to Pb from outdoor ambient air has dropped precipitously, and inhalation of Pb from the air is now only a very small fraction of a daily Pb exposure (ATSDR 2021; Gulson et al 2018).

3.5 TOYS

The vast majority of toys are not expected to present a significant Pb exposure source. Some painted or coated toys, including such things as toy jewelry, manufactured often in China, can present a significant Pb exposure risk (CPSC 1997; European Commission 2021; Schmidt 2008). The EU RAPEX dangerous non-food products notification system lists numerous toy products from China, some with Pb migration levels of up to 1442 mg Pb/kg (European Commission 2021). Although the 1997 CPSC study and accompanying Greenpeace report found exposures to some toys to represent unacceptably high Pb intakes, the majority of the toys tested had undetectable levels of Pb (CPSC 1997). The wipe test of toys in their study yielded, in one case, 0.7 μg Pb/wipe. Placed into the context of the total daily Pb intake relationship with blood Pb across all exposure sources (Figure 5), it is apparent that non-compliant toys have the potential to represent a significant proportion of daily Pb exposure. Figure 5 also illustrates the relatively constant contribution to blood Pb from diet and water sources, while the contribution from dust and soil is more varied and potentially significant.

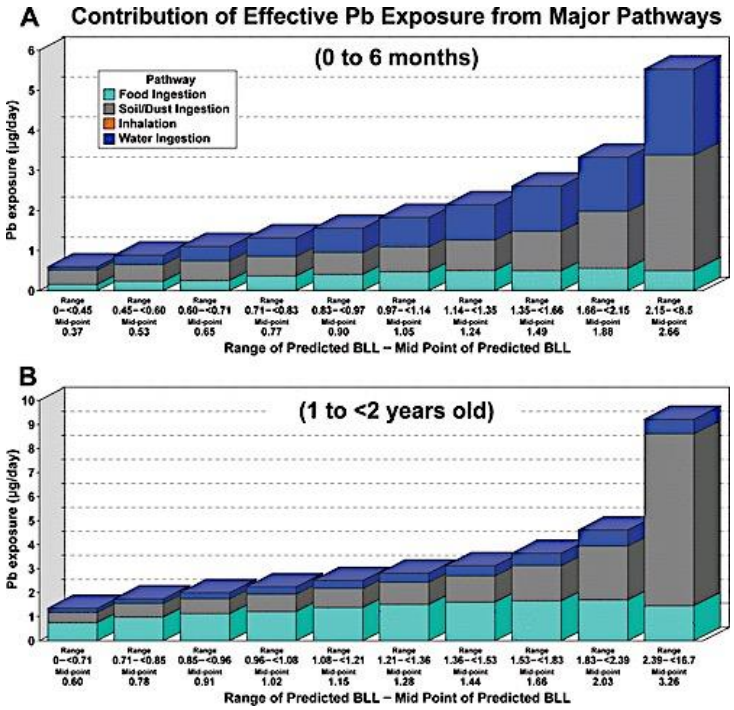
A more recent study by Igwezi and colleagues in Nigeria found Pb in all 30 toys surveyed, all sourced from China, although all of these were between 5-10% of the 90 ppm Pb regulatory limit (Igweze et al 2020). In their risk assessment, the toys contributed to a daily Pb exposure of approximately 1-2 μg/day for a 15 kg child through mouthing and swallowing Pb residues.

Figure 4. Relative contribution of environmental exposure routes to children's blood Pb using IEUBK modeling results from 108 children (1-2 year olds) in Sydney, NSW



Adopted from Gulson et al (2018)

Figure 5. Relationship between modeled Pb exposures and blood Pb in U.S. children A) 0-6 months of age, B) 1-2 years old



Adopted from Zartarian et al (2017)

4. ALLOWABLE LEVELS OF LEAD IN CHILDREN'S PRODUCTS

Regulatory limits for Pb in children's products have been developed or adopted in New Zealand and numerous countries internationally.

Most toys sold in New Zealand, and internationally, are manufactured in China and other parts of Asia. The manufacturing standards and regulatory controls over Pb and other toxic contaminants in or on the materials used in these toy products can vary, being largely governed by the desire to meet the environmental safety standards of the importing countries. In New Zealand, an Unsafe Goods (Lead in Children's Toys) Indefinite Prohibition Notice from 2009, remains in force. This limit specifies that children's toys should not exceed a 90 mg Pb/kg migration limit (Commerce Commission 2021).

Internationally, there is considerable consistency across western countries in terms of allowable regulatory limits of Pb in children's toys. Australia has a 90 mg Pb/kg migration limit for Pb in children's products (Product Safety Australia 2021). In the United States, the U.S. Consumer Product Safety Commission monitors and regulates lead contents in children's' products, including toys (CPSC 2021). Under the U.S. regulations, there are two distinct requirements concerning lead in children's products. One requirement concerns the total lead content of the children's product, while the other requirement deals specifically with the levels of lead contained in the paint or surface coating of a children's product. With a few limited exceptions, all children's products manufactured in or imported into the United States must not contain more than 100 ppm of total lead content in accessible parts.
All children's products, and some furniture, for adults and children, must not contain a concentration of lead greater than 0.009 percent (90 ppm) in paint or any similar surface coatings. Household paints must also meet this requirement. The Health Canada Consumer Product Safety Office regulates Pb in toys similarly at 90 mg Pb/kg, for the accessible part of the toys, particularly pertaining to coatings used on toys (Health Canada 2020).

In Europe, the European Toy Safety Directive of 2009 specifically limits the chemical components of children's toys with an aim to remove or limit carcinogens, mutagens, or reproductive toxicants. Directive 2009/48/EC lists allowable migration limits for numerous metals, and the limits for Pb include 13.5 mg Pb/kg (dry, brittle, or pliable toys), 3.4 mg Pb/kg (liquid or sticky toys) and 160 mg Pb/kg scraped off material (European Commission 2009).

The EU allowable limits from Directive 2009/48/EC state:

1) *"Shall not be placed on the market or used in articles, or accessible parts of articles, which are supplied to the general public and which can be placed in the mouth by children if the concentration of lead (expressed as metal) in that article, or part of article, is equal to or greater than 0.05% by weight.*
2) *For the purposes of paragraph 1, an article or part of article can be placed in the mouth by children if it is smaller than 5 cm in one dimension or has detachable or protruding parts of that size.*
3) *Paragraph 1 does not apply if an article, or a part of an article, is not accessible by children during normal or reasonably foreseeable conditions of use.*

4) *European Standard EN71-1, as adopted by the European Committee for Standardisation (CEN), shall be used, where appropriate, as the method to determine "accessible parts" of articles.*
5) *Paragraph 1 does not apply when it can be demonstrated that the rate of lead release from an article or any part of an article, whether coated or not coated1, does not exceed 0.05 µg/cm2 per hour (0.05 µg/g per hour)."* (ECHA 2013)

An amendment to this regulation came into force in 2018, lowering the respective allowable migration limits to 2.0, 0.5, and 23 mg Pb/kg for three toy categories (SGS 2017). The technical calculations justifying the amended values, which deviate from the other authoritative regulations, could not be located at the time of this report.

5. EXPOSURE SCENARIOS

The exposure estimates below are based on the assumption that a child's exposure to Pb from toys arises from the transfer of Pb from the toy to the hands and then to the mouth, and also by direct mouthing of the toy itself. Empirical studies on the bioaccessibility of Pb from toys into saliva indicate a low rate (<1%) of transfer into saliva, whereas much higher efficiency was observed with an acidic fluid (Cui et al 2015). Similarly, a survey of 72 low cost plastic toys found that 27 (37.5%) of the toys contained Pb above 100 ppm, but that the bioaccessible amount of Pb using dilute HCl was only 0.8 to 8.8%, thus satisfying the Chinese standard of < 90 ppm bioaccessible Pb (Kang and Zhu 2015). Conversely, a study in 1997 by the US CPSC found that wet wipes (composition not provided) transferred significant amounts of Pb from some toys (CPSC 1997).

Research on the transfer efficiency of Pb from lead weights to saliva found that a typical hand to mouth (saliva) transfer efficiency was 24%, whereas 50% has been used as a conservative default value (CalEPA 2011; Sahmel et al 2015). The reason for such variations in transfer efficiencies may relate to the variable physical/chemical properties of individual surface coatings, and the pH of the fluid. For the purpose of this report, a range of transfer efficiency of 1% to 24% was used to estimate Pb transfer to saliva or hands from toys.

A calculation of the internal dose of Pb received must consider bioavailability following ingestion. The amount of soluble Pb that can be absorbed orally has reportedly varied from 2 – 80% depending on the fasting state of the individual (Zia et al 2011). For the purposes of the scenarios below, an oral absorption efficiency of 30% is assumed. The U.S. EPA IEUBK model for lead risk assessments uses a default value of 30% for ingested soil Pb to be absorbed into the blood (USEPA 2021).

Dermal absorption of Pb from toys is assumed to be negligible in comparison to oral intakes.

General Equation

Exposure = ExpHM + ExpOM

ExpHM = Pb(conc) * % BA * TE * HM * Abs
ExpOM = Pb(conc) * % BA * TE * OM * Abs

Where:
Exposure = Exposure dose of Pb (per day)
ExpHM = exposure from hand-to-mouth activity
ExpOM = exposure from object-to-mouth activity
Pb(conc) = Pb level in toy or paint/coating (mg Pb/kg) = 90 mg Pb/kg
Kg(toy) = mass of toy contacted per event (kg toy) = 0.01 kg assumed
% BA (bioaccessible fraction from Cui et al., 2015)
TE = transfer efficiency (%) per contact event (assumed to be 24%, from Sahmel et al., 2016)
OM = Number of object to mouth contact events per day (events/day)
HM = Hand to mouth events per day
Abs = % absorption of Pb from oral route (assumed to be 30% as default (U.S. EPA IEUBK)

Below are three exposure scenarios that aim to capture 1) A 2-3 year old child handling and mouthing a toy with a level of Pb at the NZ allowable limit of 90 ppm, 2) a 2-3 year old child exposed to a level of Pb that has been reported in a non-compliant toy in the U.S., and 3) a 2-3 year old swallowing a small toy at the NZ allowable limit. It should be noted that these estimates relate to lead exposure from contact with lead-containing toys only and do not include contributions to lead exposure from other sources.

Scenario 1: 2-3 year old child, touching/mouthing 10 cm^2 surface area, paint/coating on 10 g toy with 90 mg Pb/kg

Object to mouth:
Exposure = 90 µg Pb/g * 10 g toy * 0.01 proportion bioaccessible (Cui et al., 2015) * 0.24 transfer to saliva (Sahmel et al., 2016) * 10 events/day (Cressey and Horn 2016) * 0.3 (IEUBK soil) = **6.5 µg/d**

Hand to mouth:
Exposure = 90 µg Pb/g * 10 g toy * 0.01 proportion bioaccessible (Cui et al., 2015) * 0.24 transfer to saliva (Sahmel et al., 2016) * 20 events/day (Cressey and Horn 2016) * 0.3 (IEUBK soil) = **13 µg/d**

Scenario 2*:* 2-3 year old child, mouthing and handling a non-compliant toy, constantly yielding 0.7 µg Pb/contact (from CPSC 1997)

Exposure = [0.7 µg Pb/contact (CPSC 1997) * 10 OM events/day * 0.3 (abs) = 2 µg Pb/day] **+** [0.7 µg Pb/contact * 20 HM events/day * 0.3 (abs) = 4 µg/day] **= 6 µg/day**

Scenario 3: 2-3 year old child, swallowing 1 g of a non-compliant toy at 90 ppm Pb/kg

Total Pb in toy = 90 mg Pb/kg * 0.001 kg = 0.09 mg or 90 µg Pb.

Exposure = 90 µg /day * 0.3 = **27 µg Pb/day** (assuming IEUBK default oral bioavailability of 30% from soils)

It should be noted that none of the above scenarios are intended to estimate typical or long-term exposures, but only rare events and short-term timeframes.

6. RISK CHARACTERISATION

The calculations above show that repeated exposures to toys containing lead at concentrations that approach the New Zealand allowable limit of 90 ppm Pb, using conservative exposure assessment assumptions, could result in a significant increase on a child's blood Pb levels, and exceed what would be considered typical Pb background from dietary, drinking water, and soils/dusts.

Table 3. Estimated daily Pb exposures from children's toys in context of common environmental sources

Exposure source	Estimated daily exposure (µg Pb/day)	Basis	Reference
Food	3	2016 NZ TDS (young adult)	NZ TDS (2018)
	2.04	IEUBK default (3-4 year old)	U.S. EPA (2016)
Water	0.4	NZ MAV (10% of MAV)	NZDWS (2021) Cressey and Horn, 2016)
	0.5	IEUBK default (3-4 year old)	U.S. EPA (2016)
Dust/soil	25[a] (highly site specific)	Urban area house dust From 1993 survey	Kim and Fergusson (1993)
Toys	0[b] - 27	Upper limit estimated under swallowing scenario	CPSC 1997; RAPEX 2021; Igweze et al., 2020

[a] based on geometric mean urban Christchurch house dusts from 1993.
[b] the majority of toys contain less than detectable levels of Pb.

Lead exposure from a toy at the 90 ppm allowable limit could result in a Pb dose of 27 µg Pb/day, that, by itself, would be expected to roughly equal the daily Pb dose resulting in a 5 µg Pb/dL (0.24 µmol/L) blood level in young child (Figure 5). The intake would also be similar to that from ingestion of house dust in urban areas. While the actual use of a given toy may only last weeks or months, the impact on neurodevelopment over a subchronic period is unknown, and daily exposures during this time could therefore pose a risk of serious harm to a developing child.

7. DISCUSSION

This report confirms that Pb in children's toys is an international concern for specific products, and highlights that product safety standards, with monitoring and enforcement are necessary to prevent excessive Pb exposures to children. While the existing allowable limit of 90 ppm Pb in children's toys is generally consistent with international standards, the EU has recently lowered its allowable Pb limits in toys. The purpose of the allowable limit is to prevent exposures that would exceed the previously existing 10 µg Pb/dL (0.48 µmol/L) blood notification level from occurring. However, because the New Zealand and international blood Pb level of concern has recently lowered to 5 µg Pb/dL, a more conservative allowable limit appears to be justified, so long as this is reasonably achievable. While some toys have been found to contain substantial amounts of lead, the limited data available on Pb in toys from surveys internationally indicates that most toys have no detectable Pb.

8. CONCLUSIONS

Children's toys, especially those manufactured overseas, have occasionally been found, in New Zealand and in other countries, to contain Pb at concentrations that can pose a risk to brain development in children. The current allowable limit in New Zealand of 90 ppm in painted or coated toys, while consistent with similar limits overseas, appears to be capable of contributing to a daily dose of Pb that is sufficient to elevate blood Pb concentrations beyond acceptable levels.

Comprehensive random surveys of Pb in toys in New Zealand are not available from which to construct an exposure scenario that would describe a population-wide, typical Pb exposure from toys. However, there is sufficient evidence from New Zealand and international regulatory actions to confirm that occasional non-compliant toy products do occur and pose a toxicological risk. Thus, while Pb exposures from toys are expected to be negligible under the vast majority of circumstances, there remains a potential for Pb-contaminated toys to present acute or chronic exposures of concern to individual children.

9. REFERENCES

't Mannetje A, Coakley J, Douwes J. 2020. Where are we at with lead? Current levels, time trend, and determinants of blood lead in New Zealand children and adults. *International Journal of Hygiene and Environmental Health* 225:

ATSDR. 2021. *What are routes of exposure to lead?* 26 May 2021. https://www.atsdr.cdc.gov/csem/leadtoxicity/exposure_routes.html#:~:text=Exposure%20to%20lead%20and%20lead,occurs%20through%20ingestion%20or%20inhalation.

Budtz-Jorgensen E, Bellinger D, Lanphear B et al. 2013. An international pooled analysis for obtaining a benchmark dose for environmental lead exposure in children. *Risk Analysis* 33 (3): 450-461

CalEPA. 2009. *Revised California human health screening levels for lead*. 26 May 2021. https://oehha.ca.gov/media/downloads/crnr/leadchhsl091709.pdf

CalEPA. 2011. *Proposition 65 Interpretive Guideline No. 2011-001. Guideline for hand-to-mouth transfer of lead through exposure to consumer products*. 26 May 2021. https://oehha.ca.gov/media/downloads/crnr/2011handtomouthpb.pdf

CDC. 2012. *CDC Response to Advisory Committee on Childhood Lead Poisoning Prevention Recommendations in "Low Level Lead Exposure Harms Children: A Renewed Call of Primary Prevention"*. 26 May 2021. https://www.cdc.gov/nceh/lead/docs/cdc_response_lead_exposure_recs.pdf

Commerce Commission. 2021. *Product safety standards – Children's toys*. 26 May 2021. https://comcom.govt.nz/__data/assets/pdf_file/0024/62583/Product-safety-standards-Childrens-toys-Fact-sheet-February-2021.pdf

Council on Environmental Health. 2016. Prevention of childhood lead toxicity. *Pediatrics* 138 (1): e20161493

CPSC. 1997. *CPSC staff report on lead and cadmium in children's polyvinyl chloride (PVC) products*. Washington: US Consumer Product Safety Commission

CPSC. 2017. Safety Standard Mandating ASTM F963 for Toys. *Federal Register* 82 (21): 8989-8993

CPSC. 2021. *Total lead content business guidance & small entity compliance guide*. 26 May 2021. https://www.cpsc.gov/Business--Manufacturing/Business-Education/Lead/Total-Lead-Content-Business-Guidance-and-Small-Entity-Compliance-Guide

Cressey P, Horn B. 2016. *New Zealand exposure factors handbook: Recommended values for use by the Institute of Environmental Science and Research Ltd (ESR)*. ESR Client Report FW16002. Christchurch: Institute of Environmental Science and Research

Cui XY, Li SW, Zhang SJ et al. 2015. Toxic metals in children's toys and jewelry: Coupling bioaccessibility with risk assessment. *Environmental Pollution* 200: 77-84

Di Gangi J. 1997. *Lead and cadmium in vinyl children's products. A Greenpeace expose*. 26 May 2021. https://files.eric.ed.gov/fulltext/ED414034.pdf

Dignam T, Kaufmann RB, LeStourgeon L et al. 2019. Control of lead sources in the United States, 1970-2017: Public health progress and current challenges to eliminating lead exposure. *Journal of Public Health Management and Practice* 25: S13-S22

Doyi INY, Isley CF, Soltani NS et al. 2019. Human exposure and risk associated with trace element concentrations in indoor dust from Australian homes. *Environment International* 133:
ECHA. 2013. *Committee for Risk Assessment (RAC) Opinion on an Annex XV dossier proposing restrictions on lead and its compounds in articles intended for consumer use*. 26 May 2021. https://echa.europa.eu/documents/10162/7e7dac2a-4eb1-83ef-d4e0-4068fd5ab063

EFSA. 2010. Scientific Opinion on lead in food. EFSA Panel on Contaminants in the Food Chain (CONTAM). *EFSA Journal* 8 (4): 1570

European Commission. 2009. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys. *Official Journal of the European Union* L170: 1-37

European Commission. 2021. *Safety Gate: the EU rapid alert system for dangerous non-food products*. 26 May 2021. https://ec.europa.eu/safety-gate-alerts/screen/webReport

Gulson B, Taylor A, Stifelman M. 2018. Lead exposure in young children over a 5-year period from urban environments using alternative exposure measures with the US EPA IEUBK model - A trial. *Environmental Research* 161: 87-96

Health Canada. 2013. *Risk Management Strategy for Lead*. 26 May 2021. https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/ewh-semt/alt_formats/pdf/pubs/contaminants/prms_lead-psgr_plomb/prms_lead-psgr_plomb-eng.pdf

Health Canada. 2020. *Industry guide to Health Canada's safety requirements for children's toys and related products*. 26 May 2021. https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/industry-professionals/industry-guide-safety-requirements-children-toys-related-products-summary/guidance-document.html

Igweze ZN, Ekhator OC, Orisakwe OE. 2020. A pediatric health risk assessment of children's toys imported from China into Nigeria. *Heliyon* 6 (4): e03732

JECFA. 2011. *Evaluation of certain food additives and contaminants. Seventy-third report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series 960*. Geneva: World Health Organization

Kang SG, Zhu JX. 2015. Total lead content and its bioaccessibility in base materials of low-cost plastic toys bought on the Beijing market. *Journal of Material Cycles and Waste Management* 17 (1): 63-71

Kim N, Fergusson J. 1993. Concentrations and sources of cadmium, copper, lead and zinc in-house dust in Christchurch, New Zealand. *Science of the Total Environment* 138 (1-3): 1-21

Lanphear BP, Hornung R, Khoury J et al. 2005. Low-level environmental lead exposure and children's intellectual function: An international pooled analysis. *Environmental Health Perspectives* 113 (7): 894-899

Leal MFC, Catarino RIL, Pimenta AM et al. 2016. Lead migration from toys by anodic stripping voltammetry using a bismuth film electrode. *Archives of Environmental & Occupational Health* 71 (5): 300-306

Ministry of Health. 2021. *Reduction in blood lead notification level*. 26 May 2021. https://www.health.govt.nz/news-media/news-items/reduction-blood-lead-notification-level

Muscat MKM. 2020. A tarnished toy story. *Journal of the International Federation of Clinical Chemistry and Laboratory Medicine* 31 (2): 174-176

NSW Health. 2018. *Lead in blood control guideline*. 26 May 2021. https://www.health.nsw.gov.au/Infectious/controlguideline/Pages/lead.aspx

NZ Herald. 2010. *Highly toxic lead levels in toys*. 26 May 2021. https://www.nzherald.co.nz/nz/highly-toxic-lead-levels-in-toys/HPN4GH4KBXWXKCG35KTIQLQDNA/

Pearson AM, Gibbs M, Lau K et al. 2018. *2016 New Zealand Total Diet Study*. Wellington: Ministry for Primary Industries

Product Safety Australia. 2021. *Toys containing lead & other elements*. 26 May 2021. https://www.productsafety.gov.au/standards/toys-containing-lead-other-elements

Public Health England. 2020. *Lead Exposure in Children Surveillance System (LEICSS) annual report, 2018* 26 May 2021. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/855722/hpr0120_LEICSS_2018.pdf

Sahmel J, Hsu EI, Avens HJ et al. 2015. Estimation of hand-to-mouth transfer efficiency of lead. *Annals of Occupational Hygiene* 59 (2): 210-220

Schmidt CW. 2008. Face to face with toy safety - Understanding an unexpected threat. *Environmental Health Perspectives* 116 (2): A70-A76

SGS. 2017. *EU strengthens lead migration in toys*. 26 May 2021. https://www.sgs.com/en/news/2017/05/safeguards-06217-eu-strengthens-lead-migration-in-toys

SNC-Lavalin. 2012. *Proposed Toxicological Reference Values for Lead (Pb)*. 26 May 2021. https://www2.gov.bc.ca/assets/gov/environment/air-land-water/site-remediation/docs/policies-and-standards/toxicological_reference_values_for_lead_tg7.pdf

Spungen JH. 2019. Children's exposures to lead and cadmium: FDA total diet study 2014-16. *Food Additives and Contaminants: Part A* 36 (6): 893-903

USEPA. 2018. *Blood lead*. 26 May 2021. https://cfpub.epa.gov/roe/indicator_pdf.cfm?i=63

USEPA. 2021. *Fact Sheet: Lead RBA and IVBA. Relative bioavailability and in vitro bioaccessibility of lead in soil*. 26 May 2021. https://semspub.epa.gov/work/HQ/100002717.pdf

USFDA. 2020. *Lead in Food, Foodwares, and Dietary Supplements*. 26 May 2021. https://www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements#:~:text=The%20FDA%20calculated%20the%20current,the%20CDC's%20blood%20reference%20level.

Winter C. 2017. *Trade Aid recalls kids toys after unsafe levels of lead detected*. 26 May 2021. https://www.stuff.co.nz/business/88885985/trade-aid-recalls-kids-toys-after-unsafe-levels-of-lead-detected#:~:text=Fair%20trade%20importer%20Trade%20Aid,of%20Trade%20Aid's%20latest%20shipment.&text=Trade%20Aid%20flute.,metal%20and%20a%20strong%20poison.

Zartarian V, Xue JP, Tornero-Velez R et al. 2017. Children's lead exposure: A multimedia modeling analysis to guide public health decision-making. *Environmental Health Perspectives* 125 (9): 097009

Zia MH, Codling EE, Scheckel KG et al. 2011. *In vitro* and *in vivo* approaches for the measurement of oral bioavailability of lead (Pb) in contaminated soils: A review. *Environmental Pollution* 159 (10): 2320-2327